

**§ 864.9225 Cell-freezing apparatus and reagents for in vitro diagnostic use.**

(a) *Identification.* Cell-freezing apparatus and reagents for in vitro diagnostic use are devices used to freeze human red blood cells for in vitro diagnostic use.

(b) *Classification.* Class I (general controls).

[45 FR 60643, Sept. 12, 1980]

**§ 864.9245 Automated blood cell separator.**

(a) *Identification.* An automated blood cell separator is a device that automatically removes whole blood from a donor, separates the blood into components (red blood cells, white blood cells, plasma, and platelets), retains one or more of the components, and returns the remainder of the blood to the donor. The components obtained are transfused or used to prepare blood products for administration. These devices operate on either a centrifugal separation principle or a filtration principle. The separation bowls of centrifugal blood cell separators may be reusable or disposable.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 864.3.

[45 FR 60645, Sept. 12, 1980, as amended at 52 FR 17733, May 11, 1987]

**§ 864.9275 Blood bank centrifuge for in vitro diagnostic use.**

(a) *Identification.* A blood bank centrifuge for in vitro diagnostic use is a device used only to separate blood cells for further diagnostic testing.

(b) *Classification.* Class I (general controls).

[45 FR 60645, Sept. 12, 1980]

**§ 864.9285 Automated cell-washing centrifuge for immuno-hematology.**

(a) *Identification.* An automated cell-washing centrifuge for immuno-hematology is a device used to separate and prepare cells and sera for further in vitro diagnostic testing.

(b) *Classification.* Class II (performance standards).

[45 FR 60646, Sept. 12, 1980]

**§ 864.9300 Automated Coombs test systems.**

(a) *Identification.* An automated Coombs test system is a device used to detect and identify antibodies in patient sera or antibodies bound to red cells. The Coombs test is used for the diagnosis of hemolytic disease of the newborn, and autoimmune hemolytic anemia. The test is also used in crossmatching and in investigating transfusion reactions and drug-induced red cell sensitization.

(b) *Classification.* Class II (performance standards).

[45 FR 60646, Sept. 12, 1980]

**§ 864.9320 Copper sulfate solution for specific gravity determinations.**

(a) *Identification.* A copper sulfate solution for specific gravity determinations is a device used to determine whether the hemoglobin content of a potential donor's blood meets the required level (12.5 grams per 100 milliliters of blood for women and 13.5 grams per 100 milliliters of blood for men).

(b) *Classification.* Class I (general controls).

[45 FR 60647, Sept. 12, 1980]

**§ 864.9400 Stabilized enzyme solution.**

(a) *Identification.* A stabilized enzyme solution is a reagent intended for medical purposes that is used to enhance the reactivity of red blood cells with certain antibodies, including antibodies that are not detectable by other techniques. These enzyme solutions include papain, bromelain, ficin, and trypsin.

(b) *Classification.* Class II (performance standards).

[45 FR 60647, Sept. 12, 1980]

**§ 864.9550 Lectins and protectins.**

(a) *Identification.* Lectins and protectins are proteins derived from plants and lower animals that cause cell agglutination in the presence of certain antigens. These substances are